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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/559,533

12/02/2005

Tadashi Okiyama

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9144

909 7590 01/02/2009  
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EXAMINER

PATEL, SHEFALI DILIP

ART UNIT

PAPER NUMBER

3767

MAIL DATE

DELIVERY MODE

01/02/2009

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/559,533	<b>Applicant(s)</b> OKIYAMA, TADASHI	
	<b>Examiner</b> SHEFALI D. PATEL	<b>Art Unit</b> 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-5,7-19,21 and 22 is/are pending in the application.
- 4a) Of the above claim(s) 8-14 and 17-19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5,7,15,16,21 and 22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 October 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Acknowledgments***

1. In the reply, filed on October 10, 2008, Applicant amended claims 1-5, 7, 15, 16, 21, and 22.
2. Applicant cancelled claim 6.
3. Examiner objected to Figure 1 as it did not contain a "Prior Art" label. Applicant provided a replacement drawing of Figure 1. Objection is withdrawn.
4. Examiner rejected claims 1 and 15 for failing to define the invention in the manner as required by 35 USC 112, 2nd paragraph. Applicant amended claims 1 and 15. Rejections are withdrawn.
5. Currently, claims 1-5, 7, 15, 16, 21, and 22 are under examination.

### ***Response to Arguments***

6. Applicant's arguments with respect to claims 1-5, 7, 15, 16, 21, and 22 have been considered but are moot in view of the new ground(s) of rejection, based on the insertion of subject matter into independent claims 1, 15, and 21 that was not previously provided in the claims.

### ***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

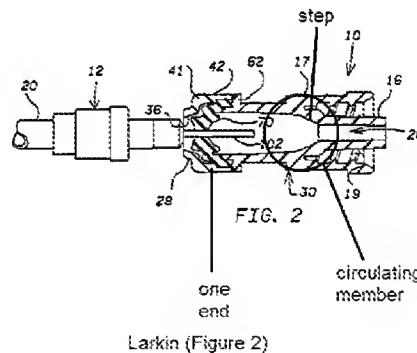
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the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-5, 15, 21, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Larkin (US 5,961,497), and further in view of Wiltse (US 3,880,401).

In regards to claims 1 and 15, Larkin teaches a mixture injection port (Figures 1-3) comprising:

- a. a channel tube unit (connector [10])
- b. a septum (seal [70]) covering one end of the channel tube unit [10] and having a slit (slit [74]) into which a tube member (cannula assembly [12]) is inserted
- c. a circulating member (*labeled in Figure 2 below*) provided in the channel tube unit [10] below the septum [70]



Larkin does not teach that the circulating member comprises a plate portion and an edge portion. Wiltse teaches a mixture injection port (Figures 1-6, valve [18]) with a circulating member comprising a plate portion (flow metering valve plug [30]) arranged to change the direction of flow of a first fluid injected from an inserted tube member (coupling nipple [16]) or a second fluid flowing from the other end of the channel tube unit (outer valve parts [22][24]) (Figure 4) and an edge portion (end wall [50]) that

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protrudes upwardly from a periphery of the plate portion [30] and is arranged along an inner wall of the channel tube unit (Figures 2 and 4). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide the circulating member, of the port of Larkin, with a plate portion and an edge portion, as taught by Wiltse, as the plate portion with the edge portion will enable the user to regulate and block fluid flow through the injection port based on the fluid needs of the patient (column 2, lines 45-55).

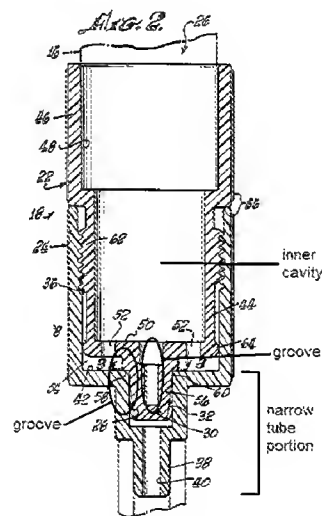
In regards to claims 2-5, in a modified port of Larkin and Wiltse, Larkin teaches that the channel tube unit [10] comprises:

- a. a body portion (housing [24]) whose opening (opening [34]) is covered by the septum [70] and that is provided with an inner cavity (central passageway [26]) for accommodating the septum that is deformed by the insertion of the tube member [12] (Figure 2)
- b. a leg portion that is provided with a narrow tube portion (tube [16]) having a smaller width than that of the inner cavity [26], wherein the narrow tube portion is configured to provide communication between the inner cavity and the other end of the channel tube [10] (Figures 1-2)
- c. a step (*labeled in Figure 2 above*) formed between the inner cavity [26] and the narrow tube portion [16]

Larkin does not teach a plate portion of the circulating member that is mounted on the step, a groove on the surface of the plate portion, a holding portion on the back face of the plate portion, or a groove on the back face of the plate portion and the holding portion. Wiltse teaches that the plate portion [30] is mounted on a step (wall surface [42])

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between an inner cavity (labeled in Figure 2 below) and a narrow tube portion (labeled in Figure 2 below). Wiltse also teaches a groove (labeled in Figure 2 below) formed on a surface on the inner cavity side of the plate portion [30], a holding portion (lower cylindrical portion [56]) on the back face of the plate portion, and a groove (labeled in Figure 2 below) on the back face of the plate portion and the holding portion. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the step, of the modified port of Larkin and Wiltse, by mounting a plate portion upon the step, as taught by Wiltse, as the plate portion will enable the user to regulate and block fluid flow through the injection port based on the fluid needs of the patient (column 2, lines 45-55).



Wiltse (Figure 2)

In regards to claims 21 and 22, Larkin teaches a method for transferring a fluid to or from a body through a mixture injection port (Figures 1-3), the mixture injection port comprising a channel tube unit [10] and a septum [70] covering one end of the channel tube unit and having a slit [74], the method comprising:

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- a. inserting a tube member [12] into the slit [74] (Figure 1 to Figure 2)  
(column 7, lines 61-63)
- b. injecting a first fluid into the tube member [12] or a second fluid into an other end of the channel tube unit [10] (column 5, lines 8-20)(column 5, lines 30-35)
- c. circulating via a circulating member (*labeled in Figure 2 above*) provided in the channel tube unit [10] below the septum [70], the first fluid or the second fluid towards the septum side (column 5, lines 8-20)(column 5, lines 30-35)
- d. guiding, via the circulating member, the first fluid to the other end of the channel tube unit [10] or the second fluid to a top portion of the tube member [12] (column 5, lines 8-20)(column 5, lines 30-35)

Larkin does not teach that the circulating member comprises a plate portion and an edge portion. Wiltse teaches a mixture injection port (Figures 1-6, valve [18]) with a circulating member comprising a plate portion (flow metering valve plug [30]) arranged to change the direction of flow of a first fluid injected from an inserted tube member (coupling nipple [16]) or a second fluid flowing from the other end of the channel tube unit (outer valve parts [22][24]) (Figure 4) and an edge portion (end wall [50]) that protrudes upwardly from a periphery of the plate portion [30] and is arranged along an inner wall of the channel tube unit (Figures 2 and 4). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide the circulating member, of the port/method of Larkin, with a plate portion and an edge portion, as taught by Wiltse, as the plate portion with the edge portion will enable the

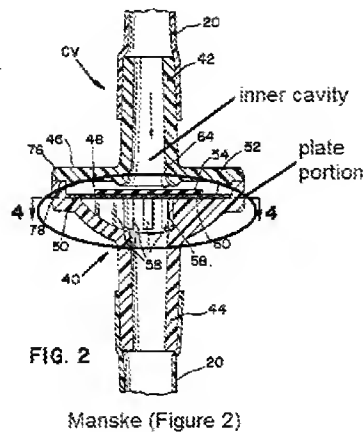
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user to regulate and block fluid flow through the injection port based on the fluid needs of the patient (column 2, lines 45-55).

9. Claims 7 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Larkin and Wiltse, as applied to claims 1 and 15 above, and further in view of Manske (US 4,141,379).

In regards to claims 7 and 16, in a modified port of Larkin and Wiltse, Wiltse does not teach a first groove on an inner circumferential surface or a second groove on an outer circumferential surface of the edge portion of the plate portion, as Wiltse does not teach any grooves on the edge portion. Manske teaches a mixture injection port comprising a plate portion (*labeled in Figure 2 below*) with edge portions (Figure 4, ribs [58]) and grooves, situated between the ribs [58]. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the edge portion, of the plate portion of the modified port of Larkin and Wiltse, with grooves, as taught by Manske, as the structure of the edge portions and grooves of the plate portion will function to guide fluid flow through the injection port and out into the patient's body through the outlet (column 3, line 68 to column 4, lines 1-2).

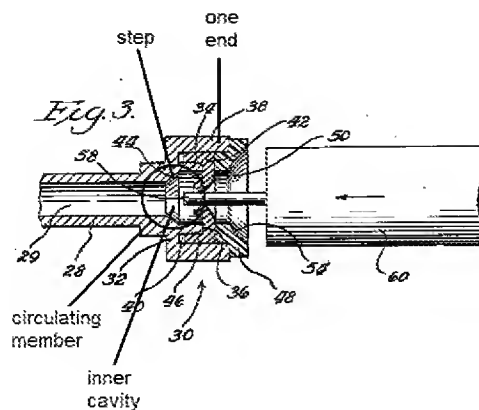




10. Claims 1-5, 15, 21, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garrett et al (US 4,197,848), and further in view of Wiltse.

In regards to claims 1 and 15, Garrett et al teaches a mixture injection port (Figures 3-4) comprising:

- a. a channel tube unit (close irrigation site [30])
- b. a septum (membrane [42]) covering one end of the channel tube unit [30] and having a slit (slit [56]) into which a tube member (syringe [60]) is inserted
- c. a circulating member (*labeled in Figure 3 below*) provided in the channel tube unit [30] below the septum [42]



Garrett et al (Figure 3)

Garrett et al does not teach that the circulating member comprises a plate portion and an edge portion. Wiltse teaches a mixture injection port (Figures 1-6, valve [18]) with a circulating member comprising a plate portion (flow metering valve plug [30]) arranged to change the direction of flow of a first fluid injected from an inserted tube member (coupling nipple [16]) or a second fluid flowing from the other end of the channel tube unit (outer valve parts [22][24]) (Figure 4) and an edge portion (end wall [50]) that protrudes upwardly from a periphery of the plate portion [30] and is arranged along an inner wall of the channel tube unit (Figures 2 and 4). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide the circulating member, of the port of Garrett et al, with a plate portion and an edge portion, as taught by Wiltse, as the plate portion with the edge portion will enable the user to regulate and block fluid flow through the injection port based on the fluid needs of the patient (column 2, lines 45-55).

In regards to claims 2-5, in a modified port of Garrett et al and Wiltse, Garrett et al teaches that the channel tube unit [30] comprises:

- a. a body portion (base [32]) whose opening (mouth [44]) is covered by the septum [42] and that is provided with an inner cavity (*labeled in Figure 3 above*) for accommodating the septum that is deformed by the insertion of the tube member [60] (Figure 3)
- b. a leg portion that is provided with a narrow tube portion (tubular branch [28]) having a smaller width than that of the inner cavity, wherein the narrow tube portion is configured to provide communication between the inner cavity and the other end of the channel tube [30] (Figures 1-2)
- c. a step (*labeled in Figure 3 above*) formed between the inner cavity and the narrow tube portion [28]

Garrett et al does not teach a plate portion of the circulating member that is mounted on the step, a groove on the surface of the plate portion, a holding portion on the back face of the plate portion, or a groove on the back face of the plate portion and the holding portion. Wiltse teaches that the plate portion [30] is mounted on a step (wall surface [42]) between an inner cavity (*labeled in Figure 2 below*) and a narrow tube portion (*labeled in Figure 2 below*). Wiltse also teaches a groove (*labeled in Figure 2 below*) formed on a surface on the inner cavity side of the plate portion [30], a holding portion (lower cylindrical portion [56]) on the back face of the plate portion, and a groove (*labeled in Figure 2 below*) on the back face of the plate portion and the holding portion. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the step, of the modified port of Garrett et al and Wiltse, by mounting a plate portion upon the step, as taught by Wiltse, as the plate portion will

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enable the user to regulate and block fluid flow through the injection port based on the fluid needs of the patient (column 2, lines 45-55).

In regards to claims 21 and 22, Garrett et al teaches a method for transferring a fluid to or from a body through a mixture injection port (Figures 3-4), the mixture injection port comprising a channel tube unit [30] and a septum [42] covering one end of the channel tube unit and having a slit [56], the method comprising:

- a. inserting a tube member [60] into the slit [56] (column 5, lines 1-5)
- b. injecting a first fluid into the tube member [60] or a second fluid into an other end of the channel tube unit [30] (column 5, lines 8-15)(column 5, lines 19-23)
- c. circulating via a circulating member (*labeled in Figure 3 above*) provided in the channel tube unit [30] below the septum [42], the first fluid or the second fluid towards the septum side (column 5, lines 8-15)(column 5, lines 19-23)
- d. guiding, via the circulating member, the first fluid to the other end of the channel tube unit [30] or the second fluid to a top portion of the tube member [60] (column 5, lines 8-15)(column 5, lines 19-23)

Garrett et al does not teach that the circulating member comprises a plate portion and an edge portion. Wiltse teaches a mixture injection port (Figures 1-6, valve [18]) with a circulating member comprising a plate portion (flow metering valve plug [30]) arranged to change the direction of flow of a first fluid injected from an inserted tube member (coupling nipple [16]) or a second fluid flowing from the other end of the channel tube unit (outer valve parts [22][24]) (Figure 4) and an edge portion (end wall [50]) that

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protrudes upwardly from a periphery of the plate portion [30] and is arranged along an inner wall of the channel tube unit (Figures 2 and 4). It would have been obvious to a person having ordinary skill in the art at the time the invention was made to provide the circulating member, of the port/method of Garrett et al, with a plate portion and an edge portion, as taught by Wiltse, as the plate portion with the edge portion will enable the user to regulate and block fluid flow through the injection port based on the fluid needs of the patient (column 2, lines 45-55).

11. Claims 7 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garrett et al and Wiltse, as applied to claims 1 and 15 above, and further in view of Manske.

In regards to claims 7 and 16, in a modified port of Garrett et al and Wiltse, Wiltse does not teach a first groove on an inner circumferential surface or a second groove on an outer circumferential surface of the edge portion of the plate portion, as Wiltse does not teach any grooves on the edge portion. Manske teaches a mixture injection port comprising a plate portion (*labeled in Figure 2 above*) with edge portions (Figure 4, ribs [58]) and grooves, situated between the ribs [58]. It would have been obvious to a person having ordinary skill in the art at the time the invention was made to modify the edge portion, of the plate portion of the modified port of Garrett et al and Wiltse, with grooves, as taught by Manske, as the structure of the edge portions and grooves of the plate portion will function to guide fluid flow through the injection port and out into the patient's body through the outlet (column 3, line 68 to column 4, lines 1-2).

***Conclusion***

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Ryan (US 6,158,458).
13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHEFALI D. PATEL whose telephone number is (571) 270-3645. The examiner can normally be reached on Monday through Thursday from 8am-5pm Eastern time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Shefali D Patel/  
Examiner, Art Unit 3767  
12/30/2008

/Tatyana Zalukaeva/  
Supervisory Patent Examiner, Art Unit 3761